

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

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Planning Guidance for Protection and Recovery Following Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) Incidents; Response-to-Comments

The Department of Homeland Security (DHS) published interim guidance for response to, and cleanup of, radiological dispersal device (RDD) and improvised nuclear device (IND) incidents. The interim Guidance, published at 71 FR 174, Jan. 3, 2006, was titled “Protective Action Guides for Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) Incidents.” This Guidance was developed by an interagency working group of the National Science and Technology Council, Committee on Homeland and National Security, Subcommittee on Standards (hereafter called the Working Group). The Guidance recommends protective action guides (PAGs) for protection of the public in RDD and IND incidents, based on PAGs published by the Environmental Protection Agency (EPA) and other agencies, and recommends the use of site-specific optimization as an appropriate strategy for developing site cleanup criteria and plans.

The general public was invited to comment on all aspects of the document. In particular, comments were invited on the following specific topics:

- Is the presentation and format of the document useful and appropriate for its intended purpose? If not, why not, and how should it be changed?
- Is the implementation process in Appendix 3 of the proposed Guidance clear and appropriate for its intended purpose? Are roles and responsibilities sufficiently defined in the document?

- Does the Guidance provide the appropriate balance between (a) public health and environmental protection goals; and (b) the flexibility needed for the decision makers to conduct emergency response actions and address public welfare needs, costs and benefits, technical feasibility and societal interests during response to and recovery from an incident? If not, how should the Guidance be changed to provide the appropriate balance?
- Are the proposed PAGs for the early and intermediate phases implementable? Are they appropriate? If not, why not and what alternatives do you recommend?
- Is the discussion on worker protection and emergency responder protection helpful? Does Appendix 1 of the proposed Guidance provide an adequate discussion of expectations and the use of the alternate response worker guidelines for life and property saving situations? If not, what additional information is needed to make the discussion adequate?
- Are the operational guidelines being developed and discussed in Appendix 4 of the proposed Guidance useful? Are the groupings clear and appropriate? Are there additional operational guides that should be developed?
- Is the optimization process proposed for late phase site restoration and cleanup reasonable and sufficiently flexible to address RDD and IND situations? If not, what changes need to be made to improve the process?
- Is a flexible process without pre-established limits an appropriate method for site recovery? Would a flexible process with goals, ranges or limits be more appropriate?
- What other guidance or tools are needed to assist in the implementation of the recommendations?

Eighty comment submissions were received on the interim RDD/IND Guidance through

April 14, 2006. The commenters included:

- One international organization
- Seven State departments of public health
- Three State emergency management agencies
- Three local and regional agencies
- Nineteen professional and nongovernmental organizations
- Thirty-eight private citizens
- Three Consulting firms

The federal interagency Working Group that developed the Guidance evaluated the comments. A summary of these comments and the Working Group's response is presented here.

1 - General Approval/Disapproval of PAGs

1.1 - Generally Approved of Guidance as Written

Several commenters generally approved of the interim Guidance, stating that the interim Guidance as written are thorough, useful, and flexible. Of these comments, several commended the interim Guidance as an excellent resource and guidance tool for emergency response planning and for direct use by emergency responders. Many comments supported the use of existing Federal guidance from the Environmental Protection Agency (EPA), and Food and Drug Administration (FDA), as part of the framework for response following an RDD or IND incident.

1.2 - Generally Approved, but believed Additional Guidance Is Needed

Several commenters generally approved of the interim Guidance, but also believed they should include additional guidance. A few of these commenters suggested more emphasis on responder and public education because the general public has no experience with RDD or IND incidents. An international organization suggested additional guidance for the period when an RDD or IND incident remains a threat but is not yet an actuality. Another group stated that the PAGs for the early and intermediate phases should be revised for an IND incident. The Working Group notes that while the Guidance was not developed to address the *threat* of RDD or IND incidents, the protective actions contained in the Guidance can be used in response to a specific threat. This Guidance was developed to provide protective action guides to support decisions about actions that should be taken to protect the public when responding to, or recovering from, an RDD or IND incident. This Guidance presents levels of radiation exposure at which the Federal Government recommends that actions be considered to avoid or reduce radiation dose to the public from an RDD or IND incident. The intended audience for this Guidance is emergency management officials at the Federal, State, tribal and local levels. The Guidance should be used in coordination with other existing response and operational guidelines, such as the National

Incident Management System (NIMS), to develop response and recovery plans prior to an incident.

Due to the vast differences in radiation exposures between an RDD and an IND incident and in response to comments received, the Working Group has recommended that separate guidance be developed for the high dose rate zones expected in an IND. In the interim, this Guidance should be used.

The Working Group agrees that public information and responder education are important elements in preparing for an RDD or IND event and encourages response planners to include these items in their jurisdictions' preparedness efforts. Training and outreach efforts are available to ensure that emergency responders are familiar with the RDD/IND Guidance. In addition, there will be an effort to incorporate this Guidance into regional and national exercises so local emergency responders will become familiar with them.

1.3 - Generally Disapproved of the Guidance as Written

Several commenters generally disapproved of the proposed Guidance as written. One of these commenters stated that the proposed early and intermediate phase PAGs did not include sufficient information for first responders on the various types of radioactive material that would be encountered, instrumentation needed for response, and steps to take during a response.

The Working Group maintains that this Guidance is not the appropriate vehicle to address these concerns. This Guidance is designed to assist in the decision to implement protective actions, but is not designed to serve as a response plan or standard operating procedures for local, State, or Federal responders. Tactical decision making prior to, during, or after an RDD or IND event should be guided by local response protocols, preparedness training and operational planning. Training is available for RDD response which includes information about different

types of radioactive materials. It is expected that specific response plans that are appropriate to a given incident will be developed by State and local agencies in preparation for such events.

One commenter stated that a lack of flexibility in the proposed PAGs would be detrimental during emergency response, but did not elaborate as to the type of flexibility that was desired. To the contrary, the Guidance was explicitly designed to provide flexibility in support of decision makers without establishing rigid standards that could impede emergency response efforts. Several commenters raised concerns that proposed cleanup levels would be inadequate and not protective of public health, resulting in exposure levels that would be too high and thus present an unacceptable level of risk. The Working Group believes these commenters misunderstood the Guidance as it was written; the early and intermediate radiation dose guidelines are flexible protective action guides for local decision makers to consider, under emergency circumstances, while weighing other factors that would influence the implementation of protective action guides, such as weather, evacuation routes and other risks. The early and intermediate PAGs do not differ from the existing guidance developed by the Environmental Protection Agency¹ (the EPA PAGs) for nuclear reactor accidents. The EPA PAGs are designed to offer flexibility to responders in determining the appropriate course of action based on the unique circumstances present at the time of a particular incident. This Guidance is consistent with these concepts.

The site-specific optimization process recommended for cleaning up the affected area will result in a stakeholder defined/approved site-specific clean up level that results in level of dose (or risk) agreed to by affected parties. This flexible approach will permit state and local decision makers to consider varying clean up approaches based on the size and scope of the

¹ Manual of Protective Guides and Protective Actions for Nuclear Incidents, EPA400-R-92-001 (May, 1992).

incident, unique characteristics of the radioactive material, incident site, technical feasibility, land uses, exposure pathways, and socio-economic considerations.

2 - Consistency and Appropriateness of Guidance

2.1 - Based on Existing EPA PAGs for Early and Intermediate Phases

Fifteen comments were received from organizations and individuals about the proposed use of the existing early and intermediate phase EPA PAGs for early and intermediate phases of RDD and IND incidents. Some of the commenters endorsed applying the 1992 EPA PAGs for response, site cleanup, and recovery following both RDD and IND incidents, while others supported the use of the 1992 EPA PAG Manual, only for RDD incident response. Among these, a State agency supported using the 1992 EPA PAGs for RDD incidents and for later phases of IND incidents because volunteer responders, Federal, State, and local governments have used EPA guidance for 20 years. In a similar show of support, a different State agency noted that most assumptions in the 1992 EPA PAG Manual were scientifically sound and protective of human health and safety.

One commenter strongly recommended developing new PAGs for both RDD and IND incidents, rather than using the 1992 EPA PAGs and another stated that the document was deficient in describing the implementation of the PAGs in the early phase of responding to an IND incident. The Working Group believes that the 1992 EPA PAGs provide an adequate technical basis for this Guidance for planning for, and responding to, an RDD or IND incident. As mentioned earlier, additional guidance is proposed for responding to IND incidents in close-in hot zones.

One State agency approved of using the 1992 EPA PAGs for early and intermediate phase activities, but recommended developing new late phase PAGs for returning the public to

previously contaminated areas. The Working Group believes that the optimization process outlined for the late phase will provide a more flexible approach to cleanup of a site when flexibility is most needed, and thus will not force the abandonment of a city against the wishes of local officials. It should be noted that in the late, or cleanup, phase PAGs are not longer applicable.

A local emergency management agency suggested modifying values found in the 1992 EPA PAGs to address the high levels of radiation that would be present after an RDD or IND incident, and recommended that victims shelter-in-place, while authorities outside the fallout area organize rescue and evacuation efforts. Similarly, another commenter recommended weighing the risks of sheltering against the risks of mass evacuation from an urban area, and recommended accounting for extreme weather conditions when making such decisions. The Working Group notes that these concerns do not require modification of the proposed Guidance; rather Federal, State, and local agencies should consider using this Guidance to develop specific operational plans and response protocols for ordering shelter and evacuation and for protection of workers in emergencies involving high radiation doses. The decision to implement public evacuation or shelter-in-place is ultimately the responsibility of local officials, who should base these decisions on all available incident-specific information, including the location of the incident, levels of radiation present, the timing of the release, current weather conditions, population characteristics, and egress and transportation logistics.

One commenter was concerned that the relocation PAG of 2 rem/year for the first year after an incident and 0.5 rem/year in subsequent years might not be applicable to a large-scale RDD incident because an RDD would likely use a long-lived radionuclide. The commenter recommended implementing additional protective measures. One other commenter suggested

setting radiation exposure limits at levels allowed by the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), rather than at higher levels allowed by the 1992 EPA PAGs. The Working Group does not agree with this recommendation because the RDD/IND Guidance must provide flexibility and scalability for decision makers to be able to respond to a wide variety of potential impacts and unique circumstances.

A State environmental agency noted that an RDD or an IND would likely be detonated without warning and would immediately impact the public, making dose assessment difficult to accomplish and population impacts difficult to predict rapidly. The agency suggested allowing flexibility in the proposed PAGs for decision makers to adjust action levels in response to available resources, areas impacted, and maximization of public safety. Indeed, this Guidance does not present rigid decision points, but was designed to be flexible, allowing decision makers the latitude to respond accordingly to unpredictable RDD and IND incidents.

2.2 - Integration with other Existing Protocols

Several commenters addressed integrating the proposed Guidance with other existing protocols. Comments included a recommendation for recognizing that the lowest reasonably achievable dose could be much higher in the event of a terrorist use of a nuclear device than during normal peace time, and a request for providing both International System of Units (SI) and English units for radiation in the document. One commenter recommended basing criteria for release of property from contaminated areas on risk/dose-based standards (e.g., American National Standards Institute, ANSI N13.12-1999, Surface and Volume Radioactivity Standards for Clearance). Commenters also requested clarification as to whether the proposed Guidance would supersede the EPA PAG Manual or be a stand-alone document.

Equivalent measures in SI units have been provided in parentheses following each measurement; however, rad and rem will remain the primary units of measurement to ensure consistency with other Federal guidance and documents. The use of a dose-based standard may be of use in developing operational guidance, such as release of property, and in fact ANSI N13.12 is being used for operational guides development. A statement has been added to the document to clarify that this Guidance will stand on its own as guidance for the specific situation of RDDs and INDs until it is integrated into an upcoming revision of the EPA PAG Manual, after which readers are referred to the EPA PAG Manual.

One commenter suggested using FDA Derived Intervention Levels to address dispersal of radioactive material in a municipal water system or a commodity handling facility. This issue is addressed in the existing 1992 EPA PAG Manual.

A State agency recommended revising the planning standards in the Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants, NUREG 0654/FEMA REP 1, to reflect new standards developed under the proposed Guidance. A second commenter recommended harmonizing these PAGs with international guidance to include justification and time duration for protective actions.

Making changes to the cited preparedness regulations is beyond the scope of this effort. With regard to the second comment, harmonization with international guidance was one of the factors that were important to the Working Group during the development of this Guidance. Although this Guidance is not identical to international guidance, it is not inconsistent. The goal was to develop the most useful and scientifically sound Guidance for RDD and IND response and cleanup, consistent with the National Response Framework.

One commenter approved of using the 5 rem dose limit for emergency workers, as given in Occupational Safety and Health Administration (OSHA) regulations, and two State health agencies affirmed that the RDD/IND Guidance takes a standardized approach to worker exposure limits, based on OSHA recommendations and requirements. A third commenter thought there were conflicts between OSHA and other Federal radiation standards, which could mean that a non-radiation worker might incur a higher dose than an emergency response radiation worker. Additional commenters stated that occupational standards and guidance in the emergency worker guidelines rely on conflicting materials from OSHA, NRC, the Department of Energy (DOE), and State radiation control agencies and suggested resolving inconsistencies so that emergency responders can develop effective plans. In addition, several commenters recommended adjusting the 25 rem Total Effective Dose Equivalent (TEDE) in Table 1 to meet the 50 rem limit recommended for life saving in International Commission on Radiological Protection (ICRP) 1990, International Atomic Energy Agency (IAEA) 1999, and National Council on Radiation Protection and Measurements (NCRP) 2000 documents.

According to the 1992 EPA PAG Manual, there is no dose limit for workers performing lifesaving duties. This Guidance remains consistent with the EPA document. However, the current guidelines are designed to accommodate potentially catastrophic situations associated with RDD and INDs. The Guidance reflects the EPA 1992 PAGs, which state that “Situations may also rarely occur in which a dose in excess of 25 rem for emergency exposure would be unavoidable in order to carry out a lifesaving operation or avoid extensive exposure of large populations.” Similarly, the NCRP and ICRP raise the possibility that emergency responders might receive a dose that approaches or exceeds 50 rem (0.5 Sv) to a large portion of the body in a short time (see NCRP Report No. 116, Limitation of Exposure to Ionizing Radiation, 1993).

Exposure to these high doses presumes that Incident Commanders have determined such exposures are justified and the emergency responders are informed in advance of the risks associated with such high exposures. The Guidance reflects recommendations found in the EPA PAG Manual, and those of the NCRP.

One commenter recommended incorporating the work of the Interagency Steering Committee on Radiation Standards (ISCORS) into the Guidance. The agencies and subject matter experts who were represented on the Working Group for the current Guidance overlap significantly with those represented on ISCORS, and ISCORS is therefore considered represented.

Numerous commenters suggested using CERCLA Superfund cleanup standards. A State emergency management agency pointed out that Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) guidance considers future use scenarios, compliance with existing standards, State acceptance, community acceptance, and cost of cleanup. Similarly, other commenters suggested using CERCLA guidance to set lower limits for optimization and occupational limits, and the ICRP to set upper limits for optimization. A State agency suggested using ICRP reference levels, along with Federal and State decommissioning regulations to create an optimization process allowing flexibility for verifying if a dose is reasonable and acceptable, or if mitigation, cleanup, and relocation activities are necessary. One commenter compared the RDD/IND Guidance with the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (40 CFR Part 192) to see if publicly funded cleanups are being held to less stringent cleanup standards. Another suggested using the decontamination procedures specified in the military guidance on Management of Equipment Contaminated with Depleted Uranium or Radioactive Commodities, (AR 700-48, DA PAM 700-

48), including isolation of contaminated materials and strict protections against use of radioactive food and water.

These standards and approaches to determining clean up levels, as well as other approaches, were carefully considered by the Working Group. The consensus of the Federal agencies involved was that for events such as these a site-specific optimization process offers decision makers the flexibility necessary given the unpredictable nature and scale of possible RDD and IND attacks. The site-specific optimization approach allows for cleanup to very low levels when the circumstances permit. However, the Working Group does not believe the Federal government should be in a position to potentially require abandonment of lands following an act of terrorism that state and local governments wish to recover, just because the cancer risk level may be higher than traditional clean up standards. This Guidance does not set a different bar based on who is funding the cleanup. Rather, it recognizes that if communities and lands are to be recovered, compromises may need to be made. The site-specific optimization process will allow local stakeholders to share in decisions about future land uses, with appropriate recovery operations, to ensure the health and safety of those returning to the affected communities.

A State environmental agency stated that the OSHA ionizing radiation standards cited in Appendix 1 are outdated, and suggested revising the standards to reflect current NRC radiation protection practices found at 10 CFR part 20. The Working Group notes that all Federal and State regulatory agencies use the 5 rem dose criterion as the limit for standard occupational radiation exposure. However, the current guidelines are designed for the catastrophic situations associated with RDD and INDs. The Guidance follows the EPA 1992 PAG Manual, which states that “Situations may also rarely occur in which a worker dose in excess of 25 rem limit for

emergency exposure would be unavoidable in order to carry out a lifesaving operation or avoid extensive exposure of large populations.” Similarly, the NCRP and ICRP raise the possibility that emergency responders might receive a dose that approaches or exceeds 50 rem (0.5 Sv) to a large portion of the body in a short time. Exposure to these high doses presume that Incident Commanders have determined such exposures are justified and that emergency responders are informed in advance of the risks associated with such high exposure operations.

A labor union recommended including three additional OSHA standards in the final Guidance: Hazardous Waste Operations and Emergency Response (HAZWOPER²) (29 CFR 1910.120); Access to Exposure and Medical Records (29 CFR 1910.1020); and, Recording and Reporting Occupational Injuries and Illnesses (29 CFR 1904) and emphasized the need for all public employees to have the same health and safety protections during RDD or IND incidents. The Guidance now references HAZWOPER, which incorporates the other standards when applicable.

One commenter noted a need for prompt notification and coordination between State and local resources, especially without coordination by a nuclear power plant licensee. The commenter recommended identifying: (1) the States’ radiation control agencies as emergency response organizations to notify promptly, and (2) a primary agency to perform accident assessment and develop protective action recommendations during RDD and IND incidents. This Guidance is intended to guide decision making by Federal, State and local officials for protection of the public and workers during response actions, not outline State or local incident response protocols for a radiological/nuclear incident.

² The primary occupational safety and health standard for emergency response is the Hazardous Waste Operations and Emergency Response (HAZWOPER) standard.

One commenter supported the proposed emergency dose limit of 10 rem to protect valuable property, pointing out that it corresponds with IAEA, ICRP, and NCRP recommendations. In addition, another commenter recommended including a wide range of science-based tools for decision-making in accompanying operational guidelines, based on the 20 years of research on the effectiveness of radiological/nuclear response strategies. Operational guidelines are being developed in a separate process by DOE. Information and resources on the development of these guidelines is available on the internet at <http://www.ogcms.energy.gov/>.

A State agency suggested that Appendix 3 of the proposed Guidance conflicts with a long-standing commitment by the Federal Government to support States during radiological emergencies, with States directing response activities, and using Federal assets as needed. The commenter recommended adoption of the nationwide REP program system already in place, because it is tested through drills and exercises and proven to work effectively. This Guidance calls for States to take the primary leadership role and contribute significant resources toward cleanup of the site for radiological or nuclear terrorist incidents below a certain threshold. The process detailed in the appendix, in which Federal agencies will work closely with State and local governments, presumes incidents of a more catastrophic nature that would be aided by Federal assistance, including funding, in line with the framework established in the National Response Framework (NRF).

One commenter suggested that the Emergency Response Guidebook be included as a reference for first responder issues, including Protective Clothing, Fire and Spill Control, Criminal/Terrorist Use of Chemical/Biological/Radiological Agents, Indicators of a Possible Radiological Incident, and Personal Safety Considerations.

The commenter also recommended adding a References and Resources section to help emergency responders develop RDD and IND response plans. The commenter suggested adding:

- The Centers for Disease Control’s (CDC) “Cooperative Agreement for Public Health Emergency Guidance;”
- The National Institute of Environmental Health Sciences (NIEHS) “Minimum Health and Safety Training Criteria: Guidance for HAZWOPER, HAZWOPER-Supporting and All Hazards Disaster Prevention, Preparedness & Response;” and
- The NIEHS “Worker Training in a New Era: Responding to New Threats.”

These resources are stand-alone guides. These and many others are available through Federal, State and local outreach and training programs.

3 - Structure, Format, and Presentation

Three general comments were received from organizations calling for improvements to the structure, format, and presentation of the proposed Guidance. These comments stated that the proposed Guidance was difficult to read and interpret (in part because of the text size and arrangement of material to meet the stylistic requirements of the Federal Register). The commenter recommended adding visual aids to illustrate differences between RDD and IND incidents, and suggested including relevant recommendations and guidance, rather than referring readers to the other documents for further information.

Efforts have been made to make the Guidance more readable within the Federal Register’s rules on the format and style of published content. As mentioned earlier, when the 1992 EPA PAGs are revised, this final Guidance will be incorporated into the revised EPA PAG Manual. The Guidance will also be posted online in a more readable format.

3.1 - Overall Usefulness and Appropriateness

Several commenters stated that the proposed Guidance presentation and format were well developed, useful, and appropriate for the document's intended purpose, with one commenter approving of the presentation because it emphasized that emergency response should be different for RDD and IND incidents. Several other commenters approved of flexibility for RDD and IND incident response in order to adjust to the situation. One commenter noted that a major difference between nuclear power plant incidents and RDD and IND incidents is that nuclear power plants regularly exercise, drill, and plan for specific types of accidents; localities cannot do the same for RDD and IND incidents. Commenters suggested including additional introductory information to the Guidance to help individuals who are new to radiological emergency response and new to using PAGs. Additional commenters stated that the Federal implementation process in Appendix 3 was particularly clear and appropriately defined roles and responsibilities.

The Working Group notes that the introductory information in the proposed Guidance, as written, provides information to individuals who are reasonably familiar with radiological emergency response. The Guidance is not designed to be a primer for general audiences. However, more thorough background and introductory information for radiological emergency responders is expected to be included in the upcoming revision of the 1992 EPA PAG Manual.

A local emergency management agency suggested modifying the preface to emphasize the primary priority of saving human life after an RDD or IND incident. The Working Group agrees with the comment and the statement was added to the discussion of the emergency responder PAGs in the final Guidance.

One commenter suggested clarifying language on responder and worker protection, specifically suggesting that the Working Group modify the phrase, “no individual should be forced to perform a rescue action that involves substantial personal risk” to state that “no individual should be forcibly prevented from performing a lifesaving or property saving action.” The Working Group has clarified that statement; however, the Working Group recognizes that not all lifesaving activities may be justified when they jeopardize the life and safety of the rescuers.

Special individual exposure guidance, often in excess of standard occupational exposure limits, is required for emergency response operations because the benefits associated with establishing control at the scene of a large radiological disaster can be so great (NCRP 2001). As recommended by national and international agencies, normally only actions involving lifesaving justify acute exposures that are significantly in excess of the annual occupational dose limit. The use of volunteers and emergency workers who are trained in performing such operations during emergencies is highly recommended, because such workers would be trained in radiation protection procedures, thereby minimizing worker exposure. Exposures during emergency operations that do not involve lifesaving should, to the extent possible, be controlled to the occupational exposure limits (NRC 1991), as should exposures occurring under non-emergency circumstances.

A State environmental agency suggested adding information to section (f) of Appendix 4, specifying the criteria to use when releasing controlled material to a still-contaminated, and uncontrolled area. The recommendations of the commenter are expected to be included in the operational guidelines, which will be made available for public comment.

A State environmental agency recommended revising the FDA Derived Intervention Levels (DILs) to account for the radionuclide that would be present after an RDD or IND incident. The Working Group does not believe that revising FDA DILs is appropriate for this Guidance. Given that there is no way to predict the type or amount of radionuclide that will be present after an RDD or IND incident, this request is beyond the scope of this Guidance.

One commenter recommended modifying Table 1, “Protective Action Guides for RDD or IND Incidents,” so that it contains separate charts for RDD and IND incidents. This commenter also recommended adding information for responding to an IND incident, including specifics on addressing elevated levels of radiation, thermal effects, and electromagnetic pulse (EMP) effects. The current version of the table contains appropriate PAGs for both RDD and IND incidents. DHS recognizes that applying the existing EPA PAGs has evident limitations with respect to INDs. The table addresses low dose range protective actions, which, in the case of an IND, applies to the largest number of affected people. However, the Working Group recognizes that INDs present an extraordinary challenge nearer to the point of detonation. As mentioned earlier, the Working Group has recommended additional work be done to develop guidance for IND hot zones nearer to ground zero, and expects this work to be done.

A commenter suggested adding a footnote to the row labeled "Mortality" in Table 1C so that acute radiation syndrome (ARS) includes an explanation that delayed effects are not taken into account in determining mortality in this table. Table 1C, “Acute Radiation Syndrome” has been deleted from the final Guidance document. The Working Group decided that the material in the table did not substantially add to the development of the Guidance or enhance the discussion on planning for the protection of radiation workers. Readers are referred to the original reference for this table, NCRP 2001.

3.2 - Clear, Plain Language

The Working Group received a few comments expressing support for the use of clear, plain language in the Guidance, including the suggestion that a plain language explanation be added to the criteria for implementing actions to help decision makers understand, consider, and explain the criteria to the general public. The commenter noted past nuclear emergencies in Chernobyl and Goiania, Brazil, where the public took inappropriate action because of lack of understanding of information about radioactive materials, and also noted that there is a tendency to implement actions at lower levels when guidance is unclear. The subject matter addressed in these PAGs tends to call for more technical or scientific language, and is intended for an audience familiar with radiological emergency response planning. The Working Group has, however, revised the document with this comment in mind, and increased the use of plain language as appropriate. According to EPA, the release of the revised 1992 EPA PAG Manual will be supported by education and outreach that will contribute to the successful implementation of the Guidance.

3.3 - Addressing RDDs and INDs Separately

Several commenters stated that the Guidance should address RDD and IND incidents separately. One commenter stated that the proposed PAGs did not adequately address the significant doses, dose rates, and size of the impacted area associated with an IND incident. The commenter recommended providing a specific early phase worker guideline of 25 rad with possible extension to 100 rad for lifesaving activities, for IND incidents. The commenter also questioned the efficacy of large-scale evacuation from areas in which the majority of dose had already been received. The commenter also pointed to modeling showing that cumulative doses in the first year following an IND incident would exceed the intermediate phase 2-rem PAG for

distances up to 100 miles from the epicenter, impacting areas up to several hundred square miles. Another commenter was concerned that the proposed Guidance would not be applicable near the epicenter of an IND incident, or to areas downwind. Similarly, another commenter stated that detonation of an IND would likely come without warning, and that the spread of the radioactive plume would happen quickly with immediate, unavoidable significant doses.

The Working Group agrees that there may be incidents, especially an IND, that could produce high radiation doses and dose rates, and that radiation deposition patterns from fallout will vary depending on numerous factors. This Guidance only provides a guide for protection of populations subject to low doses that would be found further downwind of an IND incident. As noted earlier, the Working Group has determined that separate guidance must be developed uniquely for the high dose and dose-rate zones resulting from an IND. Such guidance with associated protective actions is complicated by numerous factors in the post-IND environment; time and space do not permit this discussion here. In the interim, this RDD/IND Guidance should be used.

A few commenters recommended prioritizing lifesaving efforts in the first days following an IND incident, and suggested providing a separate index for response workers with IND-specific information. Several other comments suggested adding visual aids to illustrate the differences, particularly in fallout and radioactive decay, between IND and RDD incidents. As mentioned above, additional guidance will be developed for INDs. However, the worker guidelines for lifesaving should be the same whether the event is triggered by an RDD or an IND.

Two commenters believed that the optimization process for late phase cleanup was adequate for RDD incidents, but inadequate for IND incidents. To the contrary, the Working

Group firmly believes that the optimization process is appropriate for both RDD and IND incidents; since site-specific optimization is process-oriented, the resulting cleanup decisions can be made in the same way regardless of the initial level of contamination, the size of the contaminated area, the type of technologies to be applied, the cost of the overall cleanup, the projected future uses of the contaminated lands, or the final target cleanup goal. The decision making process will however be more complex and difficult for an IND, because an IND incident would be much larger in scope than the typical RDD incident, impact a broad range of land types or uses (urban, suburban, agricultural, etc.), affect multiple ecosystems and involve other types of hazards.

A State environmental protection agency recommended increasing PAG flexibility for IND incidents to allow necessary adjustment of action levels according to available resources, area impacted, and maximization of public safety. Another State agency suggested revisions to the dose chart for responder and worker protection during the initial and intermediate phases of an IND incident, as doses in excess of OSHA standards would be expected. Another stated that the PAGs for an IND incident should be higher than the PAGs for an RDD incident. This commenter added that PAGs for IND incidents should place more emphasis on using practical methods to maintain doses that would minimize acute radiation syndrome.

As stated earlier, the PAGs in this Guidance are not rigid standards; rather, they are approximate levels at which the associated protective actions should be considered, weighing many local and incident-specific factors. These PAGs provide the necessary flexibility to allow decision makers to implement the best possible response to be protective of emergency workers and the public. Therefore, taking protective action at higher dose levels for an IND, given particular circumstances, is consistent with this Guidance. However, the Working Group is fully

aware that additional guidance is needed for responses to IND incidents. The development of such guidance is in the planning stages.

4 – Content of PAGs

4.1 – Early/Intermediate Phase

Several commenters, including State and local agencies, suggested that the language and exposure values as presented in the Guidance should be re-examined for consistency and appropriateness with the level of response (e.g., lifesaving response vs. post-emergency missions unrelated to lifesaving missions). The Working Group agrees that these PAGs and the exposure values for various emergency response actions should be consistent and believes that the final Guidance accomplishes this goal. As stated earlier, separate guidance is being developed for IND incidents. .

A State environmental agency noted that Federal guidance, including the National Response Plan, indicates that the distinction between the early and intermediate phase will be blurred during an IND or RDD event. These two phases are likely to completely overlap, yet the PAGs indicate there will be a difference between the two. The use of response phases is simply a mechanism to describe incident circumstances and appropriate protective actions. As shown in Figure 1, (Relationship between Exposure Routes, Protective Measures, & Timeframes for Effects), and reflected in the text, the Working Group believes that the Guidance is clear on both the distinctions as well as potential overlap between the phases.

Some commenters suggested that emergency responders should not only receive medical clearance prior to responding to an incident, but should also be given the right to give informed consent. One commenter stressed that any action taken by emergency responders in an environment with radiation exposure levels greater than 25 rem should be done only on a

voluntary basis. The Working Group believes decisions regarding response worker medical clearance are best handled by the worker's employer, subject to applicable regulations. The Working Group agrees that workers subject to high radiation doses, in excess of OSHA regulations, should be on a voluntary basis and has clarified the Guidance to emphasize this.

Another commenter stated that the proposed PAGs overlook the Intermediate Phase. According to the commenter, this is the time of the greatest uncertainty, confusion, and the most interaction between the victims and the scene. The Working Group believes that, as stated in the final Guidance, this phase is clearly described and the PAGs provide the appropriate protective action guidance for this portion of an incident.

One organization stated that the guides of 2 rem for the first year and 0.5 rem for each year thereafter for the public to return to their residences is above other public exposure limits commonly used. The organization added that the underlying goal or standard be one that is protective, and then risk management decisions could justify a need to deviate from that standard as appropriate. Although the Working Group agrees with the commenter that the relocation PAG is above other public exposure limits developed for other purposes, the public exposure guideline was not intended to apply under emergency circumstances. All exposure limits depend on the particular use for which they were developed. The PAG is protective of public health and safety for the emergency contexts to which it applies.

A State agency also suggested that implementation of the PAGs for the early and intermediate phases is entirely dependent on the radiological expertise and instrumentation available at the scene. The Working Group notes that commenter's statement about the dependence on on-scene expertise and instrumentation could be true of any type of incident in which hazardous materials are released, not just RDD or IND incidents, and does not change the

Guidance. In addition, several commenters proposed that the PAGs for early and intermediate phases are appropriate for RDD incidents, but would likely not be appropriate for most IND incidents. These commenters did not find the proposed early phase PAGs to be practically implementable, but did find the intermediate-phase PAGs to be implementable. These commenters reasoned that the PAGs should be based on a broad review and analysis of exposure guidance issued by NCRP, ICRP, and other national and international organizations, rather than rely only on EPA guidance developed in the late 1980s. The Working Group emphasizes that the decision to apply EPA's PAGs for the early and intermediate phase was made after conducting just the type of broad review and analysis that the commenter recommends. Specifically, the interagency Working Group of technical experts came to the conclusion that the basis for the 1992 PAGs remained the soundest approach to radiological emergency response. On the other hand, several commenters stated that the PAGs for the early and intermediate phases are implementable. They noted that States with nuclear power reactors in their jurisdictions have used the EPA PAGs for over 20 years and successfully carried out full-scale emergency response exercises.

One commenter made several suggestions regarding specific language in the Guidance. The first suggestion was to revise a paragraph in the language about the early phase which begins with "the response during the early phase includes..." to include shelter-in-place and evacuation options. A second suggestion was to change another sentence in the early phase to include: "public training and information on how to quickly size up a building and identify radiation protective areas based on the size and mass of the building." The Working Group has included the first concept in the final Guidance. The second change, however, may be appropriate within the context of IND-specific guidance yet to be developed.

This commenter also addressed the following statement in Appendix 4, second paragraph, first sentence, which begins with "this appendix describes the examples of measurable guidelines that will be developed . . ." The commenter suggested adding specific task areas to the guidelines, including the following: acquisition and distribution of dosimetry and high range radiation survey meters to responders, shelter-in-place guidelines for the first to 48-72 hours, evacuation guidelines, exposure control guidelines, anti-contamination and decontamination guidelines, public education and public information guidelines.

As noted above, the appendix does not attempt to outline all guidelines that could be, or ultimately need to be, developed. The appendix provides examples of basic guidelines for the benefit of the reader. It is expected that State and local agencies will develop other, more detailed guidelines in preparation for response to such events.

A different commenter requested clarification of the statement which reads "when making radiation dose projections, realistic assumptions should be used so the final results are representative of actual conditions." The commenter asked what was meant by "realistic assumptions?" The final Guidance clarifies that assumptions should be developed by technical experts in coordination with the Incident Commander, based on the situation at hand. Exposure assumptions are to be representative of actual conditions and parameters rather than a hypothetical maximally exposed individual.

Two commenters noted that, because RDD and IND incidents could occur with short or no advance notice, the release may be relatively short in duration, but cleanup and recovery may take months depending on the levels and types of contamination. One of these commenters highlighted that the implementation process appears clear and appropriate for those familiar with

radiological response and recovery. The Working Group agrees with the commenters and has provided additional clarification in the final Guidance.

Numerous commenters stated that the forthcoming operational guidelines will be useful when they are developed. They thought the discussion in Appendix 4 of the draft Guidance gave a "big picture" view of access and release stages, but also believed that an incident-specific document was needed to address the details. A few commenters suggested that the operational guidelines should also include additional information. Specifically, additional information should be added in Group F: Release of Property from Radiologically Controlled Areas to the criteria used to release controlled material to an uncontrolled area, and to section (f)(iii) of the appendix - "Radiation Levels for Control of Access to Radiation Areas," to provide decontamination procedures and shelter guidelines. The Working Group agrees in part, and the forthcoming operational guidelines will address the commenters' concerns regarding sheltering guidelines. The Working Group also notes that there are existing sources which contain guidance on decontamination procedures, though the Working Group recognizes the limitation of current decontamination technologies for RDD and IND applications. States and localities should incorporate operational guidelines into their plans and procedures, and develop training for their personnel.

One commenter stated that Figure 1 appears to make the assumption that an incident will be identified as being an RDD at the onset. In reality, depending on location, time of event, and other factors, identifying the incident as an RDD may take several hours or longer. The commenter is correct in its description of likely events after an incident. Figure 1 is provided merely as an example of representative events.

One organization asked whether, under any circumstances involving either an RDD or an IND, it would be advisable to administer prophylactic drugs prior to the actual event. Generally speaking, administration of prophylactic drugs, such as potassium iodide (KI), prior to an RDD event is not advisable. The unpredictability of such an RDD/IND incident would make it impossible to know when and where to administer such drugs, even if it were advisable. On the other hand, there could be situations (such as an IND event) where HHS, in discussions with the Incident Commander, may decide that certain prophylactic drugs may be beneficial immediately following an event. In the assessment of the Working Group's subject matter experts concerning the various types of sources that would likely be used in an RDD, there are none that would benefit from the prophylactic use of KI. In all situations, great care must be exercised to assess the utility of such drugs and to minimize any adverse health effects that could occur.

The commenter also stated that there appear to be two alternative actions, each with its own concerns: (1) respond as we currently do or (2) respond and stand back. The commenter suggested that the Risk Management Framework and the three key principles of "broad context, stakeholder participation, and iteration" should perhaps be applied to mitigate these concerns, because the first responders are also "stakeholders" in RDD and IND events. The Working Group notes that the Risk Management Framework is intended for use principally in the late phase. The Guidance is not intended to instruct first responders on how to respond to RDD/IND incidents. Those instructions should be based on the procedures developed by State and local organizations. Organizations seeking additional guidance for the early phase could look to other reference sources for management of terrorist events involving radioactive materials, such as provided in NCRP Report No. 138 (NCRP 2001) and to the 1992 EPA PAG Manual and its expected revision.

One commenter recommended science-based strategies for protecting the public and responders. The Working Group believes that science was fully incorporated in the PAG development, but also that science is not the sole basis for protecting the public and emergency workers. Decision makers must also consider numerous practical, social, economic, and related factors.

4.1.1 – Responder/Worker Protection

Four commenters expressed serious reservations regarding what they perceived to be high radiation limits permitted under the current emergency responder guidelines and were concerned that such limits are inconsistent with OSHA and NRC guidelines. Another commenter noted that current guidelines in State Radiological Emergency Response Plans and other sources state that emergency workers who are dispatched for missions that potentially expose them to 25 rem or greater may only undertake the mission voluntarily.

In this Guidance levels of exposure for life-saving activities are consistent with worker dose guidelines presented in the 1992 EPA PAGs and represent a consensus of the Federal agencies who participated in the Working Group, including OSHA. The final Guidance is clear that missions involving doses in excess of regulatory standards should only be taken on a voluntary basis and with full awareness of the risks involved. The worker guidelines are not rigid limits, but rather define points at which full disclosure of the chronic and acute risks associated with high radiation doses should occur. The Guidance also recommends using the ALARA (as low as reasonably achievable) principle for radiation protection, rather than automatically defaulting to a specific limit for lifesaving efforts.

The Guidance is meant to support planning and other preparedness activities at the Federal, State, and local levels by providing general information on ways to protect workers. It

is anticipated that Federal, State, and local responders will use the information in Appendix 1 of the Guidance (and information from other sources) to develop emergency plans, standard operating procedures, and training for RDD and IND incidents. Regarding concerns about inconsistencies in the level of protection afforded to emergency responders, the Working Group notes that the NRC and OSHA regulatory limits are designed for normal, day-to-day occupational exposures and are not meant to be used for life-saving activities in high exposure level emergency scenarios.

Several commenters expressed reservations about the currently accepted radiological limits, advocating that proper risk assessments be made prior to automatically sending in emergency responders during an RDD/IND event. One of these commenters added that risk assessments should be based on actual data, rather than implausible specifications. Although the Working Group agrees that risk assessment is an important element of protecting emergency responders, there may not be sufficient time during an emergency to perform these assessments in the detail that is normally expected. In radiological emergencies some estimation of the dose and risk must be performed and the worker should be briefed on that assessment. Over time and as information is gathered, risk assessments should be increasingly relied upon for both emergency responder and public protection. Appendix 1 of the Guidance provides additional clarification about the distinction between emergency workers in occupational settings and in emergency situations.

Several commenters suggested that the proposed Guidance does not offer any clear operational guidelines or strategies for emergency response and fail to realistically define hazard boundaries. Operational protocols, such as those proposed by the commenters, are outside the scope of this Guidance.

4.1.2 Training

A local emergency management agency contended that simple measures for responder protection could be expanded to include a safety measures section. The commenter added that, in order to reduce responder radiation exposures, personnel should be rotated out of the Hot Zone. A labor union commented that health care workers must be protected when providing care to emergency responders. Another commenter claimed that the Guidance must advise the general population of decontamination measures. The Working Group agrees that these are all important considerations; however, they are outside the scope of the current document.

A State agency stated that Appendix 1 should avoid the use of legal and regulatory jargon, and another commenter suggested that Table 1B incorporate “Gamma Radiation” into the title because most emergency workers will only have dosimeters receptive to gamma radiation. The Working Group has revised the final PAGs to minimize the detailed references to regulatory authorities. The Working Group disagrees with the second comment; there is no rationale for changing the title of Table 1B.

One commenter argued that the expectation that emergency responders should receive less than 5 rem would have the effect of a significant increase in casualties in the event of an RDD or IND incident. As in any emergency situation, the Working Group believes that it is essential that the safety of both the general public and emergency responders be considered before any response action is taken. Emergency response guidance levels represent a balance between the risk to the worker and the benefit gained in public protection. Furthermore, there is not an ‘expectation’ that doses will be kept below 5 rem. Indeed, the Guidance follows the EPA 1992 PAGs, which state that “Situations may also rarely occur in which a dose in excess of 25 rem for emergency exposure would be unavoidable in order to carry out a lifesaving operation or

avoid extensive exposure of large populations.” Similarly, the NCRP and ICRP raise the possibility that emergency responders might receive a dose that approaches or exceeds 50 rem (0.5 Sv) to a large portion of the body in a short time. Exposure to high doses presumes that incident commanders determine such exposures are justified and the emergency responders are informed in advance of the risks associated with such high exposures.

One commenter recommended that provisions for exposure to high level radiation should be made in Appendix 1. The Working Group notes that this information will be included in future IND guidance.

A commenter asked for clarification on where to find guidance that addresses explosive incidents that are non-nuclear. Routine protocols would not cover events such as multiple injuries, ruptured lungs, large numbers of personnel having disorientation (inner ear equilibrium), and massive cuts on dozens of personnel due to flying window glass caused by an IND or RDD. The response to non-nuclear explosive incidents and improvised explosive devices (IEDs) are not covered in this Guidance, though the similarities in response requirements are clear.

A private company suggested that site cleanup and recovery can follow a generic checklist for the routine items and could be supplemented based on the type of radionuclides, the secondary events, and collateral damage. The Working Group agrees to some extent with the commenter and encourages State and local agencies to incorporate this into their preparedness guidance.

One commenter stated that there is an unrealistic assumption that police, fire, and emergency medical service (EMS) officers who are designated to serve as Incident Commanders have the skills and knowledge to make the decisions referred to in these PAGs. The Working

Group recognizes that Incident Commanders will need to seek out the specific radiological support they need if put in charge of responding to an RDD or IND incident. Incident Commanders should be supported by State and Federal radiological experts and other radiological professionals, and as discussed above, should carefully weigh both the risks and benefits associated with proposed emergency actions. Local jurisdictions may need to arrange agreements with neighboring Radiological Emergency Response Plan States to receive assistance. One goal of the Guidance is to encourage States and localities to develop mutual aid plans and protocols that address radiation protection during an RDD or IND incident and to develop training for personnel who are likely to serve as Incident Commanders. Providing for this training and planning is, however, beyond the scope of this Guidance.

One commenter asked if firefighters are expected to refer to these PAGs before initiating fire suppression operations. The commenter noted that most of the nation's firefighters are volunteer personnel who, in many cases, do not have training in hazardous materials. As stated earlier, the Working Group believes that emergency workers who may respond to an RDD or IND incident should have basic training in radiation protection. This includes having the proper training for using protective equipment and basic measurement equipment necessary for performing their duties.

A commenter stated that clarification of the term "alternative response worker" is necessary and suggested using the term "emergency responder" for the early phase of the incident. The Working Group is applying the terms "emergency responder" and "emergency worker" in both the early and intermediate phases. The term "alternative response worker" has been deleted.

Another commenter recommended evacuating the "High Zone" to control the dose to the

population therein. The commenter further recommended controlling access to the High Zone to limit the number of non-contaminated persons entering the most contaminated area, and excluding all nonessential people. The Working Group agrees that actions should be taken to limit the number of people entering radiation-contaminated areas.

4.1.3 – Public/Environmental Health

A State environmental agency asserted that the Guidance offers a good balance between (a) public health and environmental goals, and (b) the flexibility needed for decision makers to conduct emergency response actions and address public welfare needs, costs and benefits, technical feasibility, and societal interests during the response to and recovery from an incident. Another State agency believed that public health and environmental issues were not adequately addressed, and that specifics need to be added for the elevated levels of radiation and thermal or EMP effects accompanying an IND event. The same commenter also stated that the first responder guidelines were written as though they were directed at a nuclear power plant emergency, not a nuclear detonation.

This Guidance was developed to address the radiological hazards posed by an RDD or IND incident. They were not intended to guide response to non-radiological effects that might be produced by such an incident (e.g., EMP, or fire). The Working Group agrees that first responders may be impeded in performing traditional functions during the early phase. However, through effective education and outreach activities, drills and exercises, and well-developed response protocols, the possibility of impeded responses can be minimized.

A third agency was concerned that responders may be impeded by balancing appropriate emergency response action with less critical issues. The commenter believed that lifesaving measures, fire/damage suppression, care and transport of victims, and controlling access to the

immediate scene should take precedence over other public welfare needs, costs and benefits, technical feasibility, and societal interests during the early phase. These other concerns are better addressed in the intermediate phase, according to the commenter. The Working Group agrees that lifesaving and fire/damage suppression should be the focus of the early phase, and the Guidance reflects this priority. The site-specific optimization cleanup approach, in which local stakeholders consider public welfare needs, costs and benefits, technical feasibility, and societal interests, is designed specifically for the late phase.

One organization suggested that sheltering-in-place is likely to be more protective than evacuation, and thus recommended sheltering as the preferred protective action. Furthermore, the organization recommended that the minimum level for initiation of evacuation after a radiological terrorist event be the same as the 1992 EPA PAG Manual levels for evacuation under hazardous conditions. Two additional commenters mentioned that the threshold for sheltering the public (Table 1) should be lower than that for evacuation.

The Working Group agrees that in many cases, sheltering may be more effective than evacuation to protect the public. Whether or not sheltering is the appropriate protective action, however, will depend on the nature of the incident. Appendix C of the 1992 EPA PAG Manual recommends sheltering for projected doses anywhere between 1-5 rem, but that sheltering may take place at lower projected doses. It should be noted that decision makers have access to guidelines for exposure for both evacuation and sheltering.

One commenter stated that the level that triggers access control to radiation areas is unrealistically and unnecessarily low, and that the public should not be forced to relocate at such low exposure levels. Another commenter argued that the proposed guidelines offer the public less protection from radiation than existing standards set by the NRC and the EPA. Two other

commenters believed that the proposed threshold levels were unacceptably high and could lead to a significant risk of cancer. They believed that the current threshold levels do not adequately protect the public and first responders, and therefore should be brought in line with Superfund cleanup levels. Another commenter suggested that decontamination procedures should change based on the numbers of contaminated individuals and the extent of their exposure.

The Working Group disagrees with the commenters that the levels are too low or too high. The consensus of the Working Group was that the levels are (a) appropriate, (b) consistent with existing guidance, (c) employ the same assumptions about risks from radiation exposure and benefits of protective action, and (d) use the same principles of optimization that are the common basis for all other radiation protection guidance. Furthermore, these values can be revised downward or upward as necessary, depending on the unique characteristics of an incident. Regarding the argument that decontamination procedures should change based on the size of the contaminated population and the degree of contamination, detailed information on decontamination procedures is outside the scope of this Guidance.

One commenter mentioned that it is important to recognize the hazards inherent in disposing of contaminated wash water if washing is used as a dose reduction technique. A citizens' group advocated for strict guidelines for the interdiction of contaminated drinking water, agricultural, and food products. Another commenter stated that Table 1 needs additional details regarding food and drinking water interdiction, such as the addition of a time scale. Another commenter recommended modifying the exposure route timing for ingestion of contaminated water and/or food, given that a close proximity to the blast area could immediately contaminate any food or drink since contamination of skin or clothing could easily spread to food or drink.

The Working Group agrees with the first three commenters that the implementation issue deserves additional treatment. The disposal of contaminated water and solid waste must be factored into the environmental consequences associated with the response. PAGs for the interdiction of contaminated drinking water and agricultural and food products are contained in the final Guidance. These PAGs will not include the extent of details requested by the commenter, e.g., addition of a time scale, because this information can be found in other sources. The Working Group disagrees that proximity to the blast area would necessarily result in contaminated food and drink. Regardless, any food or beverage within a contaminated zone may be disposed of as a precaution without attempting to apply food and water PAGs, especially during the early phase; however, the PAGs could be applied. The information in Figure 1 is intended to be representative, rather than serve as a factual description of all potential RDD/IND incidents.

A State environmental agency suggested adding more guidance for the use of prophylactic drugs, specifically guidance for the use of KI and its limitations. Another commenter recommended having a generic (standardized) operating plan to conservatively protect the public and the environment when "radiation doses are not directly measurable and must be calculated based on measurable quantities such as exposure rates." Finally, a commenter suggested that the column divisions in Table 1C are too broad, especially the 200-600 rad column.

Although the Working Group agrees that guidance on KI is important, the reader is referred to the original FDA guidance on the administration of potassium iodide (66 FR 64046, December 11, 2001), rather than providing detailed guidance here. The Working Group does not agree that standardized approaches are always the most public health protective; however it

agrees that the public must be protected by estimating exposures as best as is feasible when radiation doses cannot be directly measured. The Guidance encourages the use of realistic assumptions in the absence of dose measurements. Finally, the Working Group has removed Table 1C from the Guidance, preferring to reference the original citation, NCRP Report 138, 2001.

4.2 – Late Phase and Optimization Process

Although two organizations stated that the optimization process appears reasonable and sufficiently flexible, the majority of commenters on the late phase portion of the Guidance, which recommends a site-specific optimization process, urged the Working Group to amend the Guidance to include fixed exposure bounds or goals. As examples of specific goals, one commenter suggested an upper limit of 500 mrem/year and a lower benchmark of 100 mrem/year with a lower limit of 25 mrem/year for use in the late phase optimization process; another commenter suggested that the Guidance include a range within which the optimization process should be applied, such as 15 – 500 mrem/year. An additional commenter proposed their own numeric values for site clean-up guidelines. In addition, several agencies maintained that the optimization process for the late phase may not be effective without predetermined exposure limit goals, or at least a range of acceptable limits. Some of these agencies added that the optimization process, as proposed, is too open-ended to be effective. Another group of commenters stated that a flexible process with pre-established goals would be a better approach to the remediation process. Additional commenters added that using the concept of optimization without guidelines would add to the time involved in the late phase cleanup process. The commenters believed that, at a minimum, some goals should be predetermined to give State and local agencies a target to aim for.

The Working Group believes that the site-specific optimization approach in the late phase offers the greatest flexibility to respond to the wide variations in circumstances and impacts that may be encountered in potential IND and RDD incidents, from a small contamination event confined to a building, to several dozen city blocks, to thousands of square kilometers stretching across several states. Each incident will require a site-specific approach that accounts for the nature of the incident, extent of contaminated lands and infrastructure, future land use issues, technical feasibility, public welfare needs, cost, and local public input. The Guidance also encourages consideration of radiological cleanup benchmarks, whether from Federal or State agencies, or national or international organizations, including standards, regulations and guidance that may be appropriate to the particular circumstances of an incident.

As stated, pre-established numeric criteria are not recommended because of the wide variation of potential impacts that may result from RDDs and INDs. A small incident, affecting a small area, could likely be cleaned up to very low levels; however, to clean up a large incident affecting a large area, such as a large RDD or an IND, to a pre-determined numeric goal may not be technically or economically feasible. A pre-determined cleanup number, or even a range, could be overly prescriptive and restrain flexibility of State and local officials attempting to recover an affected site and return it to productive use. The Working Group does not believe the Federal Government should require State and local governments to clean up in a manner that may force the abandonment of a city or lands impacted by terrorists. The site-specific optimization approach incorporates substantive stakeholder involvement, encourages consideration of cleanup benchmarks, and allows for development of flexible cleanup options and plans development that meets the requirements of State/local governments and affected communities, and that will most likely lead to successful recovery of the impacted city or lands.

A State agency believed that it was unfair to make State and local response agencies develop guidelines through an involved process of optimization while in the midst of responding to a radiological terrorism event. Another State agency argued that decision makers will need more than a loose framework to derive sound policy and gain public confidence. The same commenter believed that setting uniform cleanup standards should remain a Federal responsibility. A third State agency stated that, without clear goals or a commitment from the Federal Government to pay for decontamination to a certain standard, the costs of cleanup and disposal will likely dictate the level of release for unrestricted use. According to the commenter, this issue may wreak havoc in the decision making process. Therefore, an optimization process must provide for a complete, defensible, and final decision by all parties, including the Federal Government, and leave no room for doubt about cleanup levels, potential health risks, or the standards used in the decision to release or restrict public use of property.

Regarding the first comment, the Working Group expects States to plan and prepare for incidents before they occur, including how contamination will be dealt with. This is consistent with Federal, State and local planning for other types of incidents, both natural disasters and accidents. This planning/preparedness process has worked for response officials located near large industrial facilities and in areas prone to natural disasters such as flooding, hurricanes, and tornados. In response to the second comment, the Working Group believes that by establishing a Federally-recommended process, State and local officials have the opportunity to be a significant partner in an integrated, informed decision making process. Concerning Federal payment, the Federal Government has never agreed in advance to pay for cleanup activities as a result of either a natural or man-made disaster. However, nothing precludes the Federal Government from committing funds for cleanup as part of a recovery. While cleanup costs are a very important

consideration in the optimization process (it may be cheaper to isolate an area than to remediate it), other types of costs and benefits, such as returning to one's home or school or place of business, may be just as important. The increased risk of stress associated with being away from home may exceed the incremental risk associated with a lower cleanup level. Thus, cleanup costs alone should not determine the cleanup level, but numerous site-specific and socio-economic factors should also be carefully weighed. Such factors will be identified by the technical and stakeholder groups during the optimization process. The Working Group agrees that the optimization process must provide an open and defensible decision.

Several commenters addressed various aspects of the optimization process. A State agency supported the concept of site-specific optimization, but expressed concerns about its implementation and the coordination of stakeholder groups. Another agency similarly supported the concept of optimization, but articulated that, without predetermined goals and numerical thresholds, competing interests of stakeholder groups would lead to substantial delays in the cleanup process. A State agency suggested more guidance be provided to explain how to work through the optimization process. One other commenter recommended that additional guidance or references to existing optimization processes be provided as a template, especially given the goal of developing the initial optimization process within six months of the incident.

The Working Group realizes that implementation and coordination of stakeholder groups will place time and energy demands on officials. Competing interests will be a concern whether an optimization process is used or not. The Guidance provides a risk management framework in Appendix 2, and basic guidance on implementing optimization. The Guidance also recommends consideration of benchmark standards and criteria. Ultimately, what will make the optimization

process successful will be the inclusiveness of the process and the technical rigor of the supporting analyses.

One organization did not believe it was appropriate or necessary for stakeholders involved in the optimization process to re-examine the fundamental radiation protection standards that have already been developed by national and international experts. Another commenter suggested that major metropolitan areas identify in advance the stakeholders that may participate in the optimization process. One commenter argued that it was important to include people who are not strongly invested in the linear no-threshold hypothesis when appointing technical advisory committees, while another requested that community members be included as local stakeholders. The Working Group agrees with the commenters. The Guidance does require that States and their stakeholder groups re-examine radiation protection standards, especially for their use as benchmarks. Membership in the advisory committees and working groups should represent a balance of technical perspectives as well as interests associated with the land use (residential, commercial, industrial, tourism, historic value, etc.), and organizations concerned with public welfare, including employment, education, and public safety. Moreover, States and localities might want to establish such groups to advise decision-makers for incidents other than RDD and IND incidents.

One commenter recommended that site restoration and cleanup should be accomplished following an act of terrorism using the available DOE Documented Safety Analysis (DSA) data accounting for facility/site design and features incorporated to simplify decontamination and increase the potential for a timely reuse/reactivation of equipment, systems, and structures. The commenter also recommended that the Working Group quantify the statement that an RDD would be the same order of magnitude as a nuclear power plant accident.

The commenter is correct to the extent that DOE procedures would need to be used for an incident at a DOE facility. Describing the DOE regimen, however, would be too detailed for inclusion in this Guidance. The Working Group has deleted the statement concerning the magnitude of RDD and nuclear power plant accidents from this final Guidance.

4.3 – Long-Term Consequences

Several commenters addressed long term consequences of an IND or RDD incident. A few commenters, including a local emergency management agency, suggested the concept of designating a “Long Term Exclusion Zone” to indicate that life-threatening radiation will be a factor in recovery, unlike recovery from a natural disaster. Another commenter questioned which exposure pathways need to be considered (ground contamination, foodstuffs, drinking water, etc.) and whether the doses from such pathways should be considered independently or cumulatively. The commenter suggested that more references and recommendations be provided in this area.

The Working Group agrees with the commenters that the impacted area will need to be divided based on the radiation levels present. Some areas will need to be controlled for longer time periods than others and these determinations will have to be based on the unique characteristics of the incident. Regarding which exposure pathways need to be considered, the Working Group notes that the particular pathways and exposure parameters depend on site-specific factors and proposed land uses, but all relevant pathways should be included in risk assessments.

A few organizations suggested that, even though a wide range of RDD scenarios is possible, a numerical range should still be offered for a long-term cleanup standard. As noted earlier, the Working Group does not believe that the decision-makers are best served by

providing numeric cleanup values, because they could be restrictive when flexibility is most needed to accomplish cleanup and recovery. But, the Working Group encourages referencing existing radiological regulations and guidance as benchmarks in the optimization process.

Several commenters stated that the proposed long-term dose limits would result in an unacceptably high cancer risk for the general public, and echoed other comments that the Guidance should be revised to use EPA Superfund cleanup standards. Expressing a contrary view, another commenter suggested that radiation in low or moderate doses may actually be beneficial to health, rather than lead to an increased risk of cancer. The Guidance, does not propose long-term exposure limits.

5 - Commenters Proposing Additional Topics for the Guidance

5.1 - Availability of Radiation Monitoring Capabilities

Several commenters stated that the use of radiation detection and monitoring equipment should have received additional consideration in the Guidance. Four commenters stated that the Guidance should not assume that there will be radiation detection and monitoring equipment available for first responders at the onset of an RDD or IND incident. Two commenters supported the use of radiation detection and monitoring equipment, but were unsure if such equipment is currently suitable for responding to an RDD or IND incident. Two other commenters emphasized that there are alternative protective actions, such as evacuation, that should occur prior to the use of radiation monitoring.

The purpose of this Guidance is not to inform the reader on the use of radiation detection equipment. The early and intermediate PAGs are not based on any assumption that radiation detection and monitoring equipment will be available at the onset of an RDD or IND incident. The PAGs do assume that State and local response organizations would revise their plans and

procedures to make radiation detection and monitoring equipment available in support of radiation protection during an incident. Regarding the final comment, the Working Group agrees that protective actions can, and should, be made prior to the availability of field measurements where appropriate. This would be the case for any sudden incident in which protective actions must be taken promptly to be effective.

5.2 - Education/Training for Response and Medical Personnel

Numerous commenters stated that additional education and training for response personnel should be incorporated into the Guidance. A few commenters supported prioritizing training for local responders above that of the Federal Government and the general public, because the local responders will be the first on the scene of a radiation incident. Several others supported the notion of adding emphasis on education in order to provide a clear understanding of RDD and IND incidents with comprehensive planning in advance of such an incident. Additionally, a local emergency management agency expressed the need for widespread public education, media relations, and Public Information Officer (PIO) operations.

Even though this Guidance is not intended to provide training information, the Working Group agrees that training, drills, and exercises for local response personnel and volunteers (*i.e.*, fire, emergency medical service, law enforcement, public health, emergency management, public works, hazardous materials, hospital and other medical personnel) are essential to an effective response to an RDD or IND incident. Everyone who would potentially be involved responding to an RDD or IND incident needs training to ensure they have the knowledge, skills and abilities to perform their duties. It would be optimal to have integrated training activities which involve Federal, State and local officials and the private sector.

A few commenters commended the current Guidance and believed that additional

funding should be made available to provide background information to responders and the public. Several commenters requested that additional funding be devoted to RDD/IND Guidance implementation, training, drills, and exercises for responders at all levels.

As noted above, a comprehensive training and outreach effort is anticipated after the publication of the revised 1992 EPA PAG Manual.

5.3 - Radiological Terrorism Event as a Crime Scene

A few commenters stated that the Guidance should evaluate the need to balance local responder needs to respond to affected public, environment, economic, and general health and safety, and the Federal Bureau of Investigation's (FBI's) needs to investigate a crime associated with the terrorist incident. One of these commenters stated that State and local officials are not familiar or experienced with responding to events that would involve the FBI. Another of the commenters recommended adding to the PAGs information specific to crime scene investigation, preservation of evidence, and interaction between Unified Command and the FBI, because State and local responders do not have experience responding to radiological terrorism.

The inclusion of information specific to law enforcement operations and criminal investigations is outside the scope of the Guidance. The need of law enforcement coordination during terrorism incident response in early and intermediate phases needs to be in accordance with the National Incident Management System (NIMS) for cases of terrorism. If an RDD or IND incident occurs at a Federal facility or involves Federal materials, the representatives in the Unified Command may change appropriately and the response will be according to procedures.

5.4 - Medical Management for Mass Casualty Events

Several commenters stated that the Guidance should include additional language regarding medical mass care. One agency identified a number of issues that should be

mentioned when providing guidance on mass casualty scenarios, including setting protection levels for pregnant women. Another supported language that included specific lifesaving actions as a top priority. One commenter believed that the Guidance should speak to the need for a certain level of control over the concerned public, which will demand immediate mass care. Additionally, other commenters supported the idea that the Guidance should focus additional attention on the psychological impact of an RDD or IND attack.

Medical management for mass casualty events is not the purpose of this Guidance. Medical management for large radiological and nuclear incidents is being addressed at the Federal level by DHS and the U.S. Department of Health and Human Services (HHS). Protection of pregnant women and injured individuals are also important issues and they are being addressed in other guidance provided by HHS. HHS has created a Radiological Event Medical Management web site (<http://www.remm.nlm.gov>) primarily to provide guidance for health care providers about clinical diagnosis and treatment during mass casualty radiological/nuclear events. Although the Working Group agrees with the commenter that lifesaving should be the top response priority, lifesaving actions needs to be considered with the risk to the emergency responders. Although an RDD or IND attack would present serious psychological implications for the public, consideration of such effects is not within the scope of this Guidance.

One commenter stated that the levels presented in the Table 1 may not be appropriate for RDD and IND incidents. To the contrary, the Working Group has determined the values in Table 1 to be an appropriate application of current practice and guidance, with the exception, as noted earlier, of the near-in high radiation zones following an IND.

5.5 - Other

Numerous organizations and individuals provided comments on a wide variety of topics indirectly related to the Guidance. These comments range from questioning the use of traditional guidance in the drafting of the Guidance to private industry offering their products in support of these PAGs.

- One commenter presented the linear no-threshold (LNT) theory to demonstrate the biphasic dose response curve and was disappointed that the document does not recognize current radiation protection standards based on the LNT theory.
- Two commenters requested that the Working Group keep records of exposures, injuries/illness, training, monitoring techniques, lessons learned and post them on the Working Group web site.
- One commenter suggested the need to perform surveys of remote locations contaminated by persons fleeing the scene.
- One commenter suggested the following: (i) members with fallout shelter operations and exposures control backgrounds should be added to the work group; (ii) fallout radiation and decay should be described; and (iii) electromagnetic pulse be added to the list of IND effects.
- One commenter pointed out that the FEMA Radiological Emergency Preparedness Handbook intended to replace the Radiological Emergency Preparedness Exercise Manual has not been issued.
- Two commenters expressed concern about the radioactive waste transported by truck each year, which is an easy terrorist target.
- One commenter requested an additional section showing agency integration to prevent functional redundancy.

- One commenter offered a product described as a first responder kit for human skin decontamination.

The Working Group notes that these comments are beyond the scope of this Guidance.

6 - Impact on States, Counties, Municipalities, and Utilities

Numerous commenters, including several State agencies, believed that the Guidance should be written with the understanding that the immediate response to an RDD and IND incident will be a bottom-up approach, with State and local agencies responding first, followed in turn by Federal resources. One agency expressed concern that the Guidance is written with the assumption that the Federal response will be immediate when it could possibly be hours away. Additionally, the commenter believed that there needs to be consistency at the Federal level in terms of defined roles and Medical Emergency Radiological Response Team (MERRT) radiological training. A State health agency was concerned that, similar to the NUREG-0654/FEMA-REP-1, Rev. 1 (Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants) and the EPA PAG Manual, the Guidance will evolve into de facto rules, with the possibility that if States and local agencies do not follow the Guidance, they will be ineligible for FEMA funding. In a related comment, another organization stressed the need for making additional sources of funding available to State and local responders.

This Guidance states that the initial response to an IND or RDD incident will be conducted by State and local first responders. This is established in the NRF and is followed in this Guidance. That said, Federal resources should be flowing quickly to support the State and local response. The NRF, with the Nuclear/Radiological Incident Annex, will guide the integration of Federal, State, and local resources for RDD and IND incidents. The Working

Group does not agree with the comment that the Guidance will become de facto rules. The current EPA PAGs have been in existence for over 20 years and they have not become regulations, although, they have been widely adopted by Federal, State and local decision makers for use in their response plans and procedures. The Working Group does not agree with the comment about the effect on State and local agencies' funding. The Guidance is not designed to be used to determine eligibility for either response or recovery funding.

Several commenters emphasized that proper guidance must be developed by incorporating the Federal response into the State and local framework, and not the other way around. The commenters identified the Nuclear Incident Response Team (NIRT) as a State-controlled capability. In addition, two commenters requested additional discussion on how the Federal response will integrate with the established State and local response, and clarification on which agencies will take the lead on specific tasks. As stated above, this Guidance is designed to be compatible with the NRF. Also, in radiological incidents, NIRT assets are under the authority and control of DHS, pursuant to the Homeland Security Act of 2001.

A State environmental agency disagreed with the comments above and believed that the process is reassuring in that the Guidance allows for joint decision making at all levels. This organization, as well as another State environmental agency, found the response and recovery overview useful as well, but asked which specific scenario would result in the State as the lead agency. This commenter was also concerned that the technical work group for the optimization process will not include the needed full stakeholder participation. Noting that the Guidance calls for the Federal Government to take the lead throughout this process, the commenter believed that this could preclude certain other groups from taking an active participatory role.

The Working Group believes that the Federal Government's role is to support the State and local decision makers and does not anticipate assuming control over the cleanup. The Guidance has been modified to make this clear. In some incidents, Federal agencies may have statutory authorities which must be applied in the decision making process. The Federal Government must work hand-in-hand with State and local decision makers to develop and implement the best possible cleanup.

The Working Group notes that the optimization process is open and transparent, and that the technical work group will be constituted by the appropriate experts. The Working Group also notes that the technical working group is not intended to include stakeholders; a companion stakeholder working group is designed expressly for stakeholder involvement. Indeed, the purpose of the optimization process is to assure a diversity of input to guide the way to the most effective recovery.

On the issue of State and local resource availability, a local emergency management agency stressed the need to incorporate the resources of States with those of nuclear power plants. The agency noted that nuclear power plants already have personnel and equipment to address a radiological incident. One organization noted that State and local authorities do not have the resources available for long-term cleanup. Therefore, according to this commenter, the Federal Government should plan to assume responsibility for cleaning up RDD and IND terrorist events, such as those presented in the Guidance. A State emergency services organization stated that Appendix 3 does not adequately address the full assets and capabilities that States bring to the response, thus creating a large gap in the implementation of the plan.

It is reasonable to consider the resources of nuclear power plants as a useful supplement to a governmental response, if available and appropriate. Available private resources should be

factored into State and local plans and procedures. Although State and local resources might not be adequate to fund a cleanup, these entities must be actively involved in the decision-making and implementation. Mutual aid agreements may be drafted between nuclear power plants and other States or local agencies. The Working Group also notes that it is not the goal of Appendix 3 to delineate the complete role of State and local officials in the response or to identify all potential resources. Rather, the Appendix aims to provide an overview of the Federally-recommended cleanup approach.

A local emergency response organization asked why they had not been consulted in the drafting of this Guidance. As stated above, the Working Group consulted with a limited number of State radiological experts, who thereby contributed to this Guidance. The public comment process provided for broader stakeholder input.

One commenter suggested that the State and local agencies need to be intimately involved up-front in the planning process and not as an afterthought, and also recommended intermediate phase examples could help, clarifying the "immediate intermediate" actions from the "non-critical" actions. The Working Group agrees that State and local agencies need to be intimately involved in all levels of planning and preparing for responding to RDD/IND incidents. The Working Group encourages State and local agencies to utilize this Guidance in their planning and preparedness.

The same commenter suggested that focused response, allowing for a vast number of potential targets and dynamic circumstances, is "almost impossible," because nuclear reactors are located in semi-rural settings, and chemical facilities are not. Research reactors are located in the middle of a college/university campus, in the heart of a town or on its outskirts, usually near main roads that are congested at peak hours of the day. These scenarios need to be addressed in a

generic fashion to foster State and local involvement in the planning stages. The Working Group does not agree with this comment, and no change has been made to these PAGs.

7 - International Collaboration

An international agency stated that international notification should be a necessary component of the Guidance because it is required under the terms of the Convention on Early Notification of a Nuclear Accident. The Working Group believes that the inclusion of international notification is beyond the scope of this Guidance.